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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,657	04/16/2001	Nathalie Garcon	B 45158	2235

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT PAPER NUMBER

1648

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,657

Applicant(s)

GARCON, NATHALIE

Examiner

Zachariah Lucas

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2004.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-37, 39-62, 71-116 and 118-141 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32-37, 39-62, 71-116 and 118-141 is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 32-37, 39-62, 71-116, and 118-141 are currently pending in the present application. In the prior action, mailed on April 20, 2004, claims 32-37, 39, 40, 42, 44-62, 115, 116, 118, and 119 were indicated as allowable; claims 41, 43, 71-81, and 93-114 were rejected; and claims 82-92 and 120-125 were objected to. In the Response submitted on September 15, 2004, the Applicant amended claims 41, 43, and 71-114; and added new claims 126-141.
2. The claims are found to be allowable, having overcome all outstanding rejections and objections.
3. This application is in condition for allowance except for the following formal matters:
The specification of the application is objected for the reasons set forth below, and in the prior actions.

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

Specification

4. **(Prior Objection-Maintained)** The specification was objected to as failing to provide proper antecedent basis for the claimed subject matter. The specification does not provide any antecedent basis for the claim limitation regarding immunostimulants “wherein the

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immunostimulant is not a saponin derived from the bark of Quillaja Saponaria Molina.” The Applicant continues to traverse this requirement by arguing that there need not be *ipsis verbis* support for the claimed subject matter, and asserting that the meaning of the terms in the claim are clear.

First, it is noted that there has been no assertion that the claimed terminology is uncertain. This argument is therefore found unpersuasive.

The second argument is that the application need no provide *ipsis verbis* support. While the Examiner agrees with this assertion, it is Office policy that the claimed inventions must have antecedent basis in the description portion of the application. While the Examiner agrees that the application provides support for embodiments wherein the immunostimulant is other than a saponin, there is no antecedent basis or recognition in the description of the application of a genus of inventions comprising adjuvant compositions comprising any immunostimulant other than a saponin. Thus, while *ipsis verbis* support is not required, in the present case there is no recognition in the description of the claimed genus of inventions as opposed to inventions comprising any one immunostimulant, or any immunostimulant (including saponins and all other immunostimulants).

As noted by Applicant, 37 CFR 1.75 requires that the claims “must conform to the invention as set forth in the remainder of the specification and the **terms and phrases** used in the claims must find **clear support or antecedent basis** in the description so that the meaning of terms in the claims may be ascertainable by reference to the description” (emphasis added). As noted above, there is no clear support for the phrase “wherein the immunostimulant is not a saponin.” While the meaning of the individual terms may clear, there is nothing in the

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description from which those in the art would have ascertained a subgenus of the claimed inventions comprising any immunostimulant other than saponins as is defined by the phrase forming the basis of this objection.

Because there is no antecedent basis in the application for the claimed invention, the specification is objected to. The objection is maintained for the reasons above, and the reasons of record.

5. **(Prior Objection- Withdrawn)** The disclosure is objected to because of the following informalities: The Applicant indicates on page 21 of the Response that the RTS, S antigen includes both the CS protein of *P. falciparum* and the S antigen of hepatitis B. The Applicant traverses the objection for the reasons presented on page 24 of the Response (i.e. that RTS is a single hybrid protein, whereas RTS,S is a combination of two proteins- the RTS hybrid, and the S protein). In view of the Applicant's comments, the objection is withdrawn.

Claim Objections

6. **(Prior Objection- Withdrawn)** Claims 71-81 were objected to because of the following informalities: These claims each identify Hib and LnRH(GnRH) as antigens that may be used in the claimed invention. In view of the amendment of the claims to provide the full name of LnRH(GnRH) the objection is withdrawn.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. **(Prior Rejection- Withdrawn)** Claims 41, 43, 71-81, and 93-114 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic compositions, does not reasonably provide enablement for vaccines against all of the identified pathogens. Claims 41, 43, 71-81, and 104-114 have been amended such that they no longer read on the rejected material.

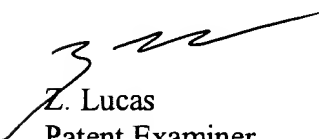
Conclusion

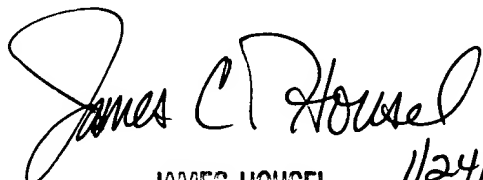
9. All claims are found allowable.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner


JAMES HOUSEL 1/24/05
SUPERVISORY PATENT EXAMINER
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